IN THE CIRCUIT COURT
THIRD JUDICIAL CIRCUIT
MADISON COUNTY, ILLINOIS

PATTY FOREMAN,

Plaintiff,

vs.

MERCK & CO., INC., also d/b/a MERCK, SHARP AND DOHME and d/b/a MSD SHARP & DOHME GmbH,
Serve: CT Corporation
208 LaSalle Street,
Suite 814
Chicago, IL 60604

G. D. SEARLE LLC,
Serve: Registered Agent
CT Corporation System
208 So. LaSalle St., Suite 814
Chicago, IL 60604

PHARMACIA CORPORATION,
Serve: Registered Agent
CT Corporation System
208 So. LaSalle St. Suite 814
Chicago, IL 60604

MONSANTO COMPANY,
Serve: Registered Agent
Illinois Corporation Service C
801 Adlai Stevenson Dr.,
Springfield, IL 62703

PFIZER INC.,
Serve: CT Corporation System
208 S. LaSalle St., Suite 814
Chicago, IL 60604

WALGREEN CO., d/b/a WALGREENS,

Serve: Alan M. Resnick

Foreman

Civil Action No. 06L854

EXHIBIT 1

200 Wilmot Road)
Deerfield, IL 60015)
)
Defendants.)

PLAINTIFF'S ORIGINAL COMPLAINT

COMES NOW, GOLDENBERG HELLER ANTOGNOLI ROWLAND SHORT & GORI, P.C., and on behalf of the above-named Plaintiff files this Complaint complaining of Product Defendants and Pharmacy Defendant for cause of action would respectfully show this Honorable Court the following:

THE PARTIES

1. PATTY FOREMAN, Plaintiff herein, is a resident of Edwardsville, Illinois. Plaintiff brings this action to recover for personal injuries Plaintiff sustained as a result of ingestion of and exposure to Defendant's drug products Vioxx and Celebrex.

2. Defendant Merck & Company, Inc. is a New Jersey corporation with its principal place of business at One Merck Drive, Whitehouse Station, New Jersey, 08889-0100. Merck & Company, Inc. is a foreign corporation doing business in the State of Illinois and maintains an office and/or other facilities within this Judicial District. Merck & Company, Inc., conducts business in the United States and Canada as Merck & Company, Inc., outside of the United States and Canada Merck conducts business as Merck, Sharp and Dohme, LLC, with the exception of Germany where it conducts business as MSD Sharpe & Dohme, GmbH. Collectively Defendants will be referred to as "Merck." Merck manufactured, tested, distributed, marketed, and/or sold the drug rofecoxib under the brand name Vioxx for the treatment of pain associated with osteoarthritis, rheumatoid arthritis, acute pain and menstrual pain. Merck may be served with process through its

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registered agent, CT Corporation System, 208 La Salle Street, Suite 814, Chicago, Illinois 60604.

3. Defendant G.D. Searle LLC. (hereinafter "Searle") is a subsidiary of Pharmacia, Corporation, and is a Delaware Corporation, and is registered to do business, and with its principal place of business, in Illinois. As such, Searle can be served its registered agent: CT Corporation System, 208 So. LaSalle St. Suite 814, Chicago, Illinois 60604. At all times relevant hereto, Searle as a subsidiary of Pharmacia, Corporation and Pharmacia Corporation (hereinafter "Pharmacia"); at all times relevant to this action was in the business of manufacturing, marketing, selling and distributing the pharmaceutical product Celebrex (Celecoxib).

4. Defendant Pharmacia is a Delaware Corporation licensed and registered to do business in Illinois and can be served through its registered agent: C T Corporation System, 208 So. LaSalle St. Suite 814, Chicago, Illinois 60604.

5. Defendant Monsanto Company (hereinafter "Monsanto") is the parent of Pharmacia, and is a Delaware Corporation. At all times relevant hereto Monsanto through its subsidiary companies was in the business of manufacturing, marketing, selling and distributing the pharmaceutical product Celebrex (Celecoxib). Monsanto is licensed and registered to do business in Illinois, and may be served through its agent: Illinois Corporation Service C, 801 Adlai Stevenson Drive, Springfield, Illinois 62703.

6. Defendant Pfizer Inc (hereinafter "Pfizer") is a Delaware corporation, and at all times relevant hereto Pfizer was in the business of marketing, selling and distributing the pharmaceutical product Celebrex (Celecoxib). Pfizer is licensed and registered to do

business in Illinois and may be served through its agent: C T Corporation System, 208 So. LaSalle St. Suite 814, Chicago, Illinois 60604.

7. Defendant, WALGREEN CO., hereinafter referred to as "Walgreens," is a corporation organized and existing under the laws of the State of Illinois, with its principal place of business in Illinois. At all relevant times, Walgreens was in the business of promoting, marketing, and distributing the pharmaceutical VIOXX. Said entity does business in Illinois and at all relevant times it promoted, marketed, and distributed the drug in question in Illinois. Defendant, Walgreens may be served by serving its registered agent, Alan M. Resnik, 200 Wilmot Road, Deerfield, IL 60015.

DISCOVERY RULE AND FRAUDULENT CONCEALMENT

8. The nature of Plaintiff's injuries and the relationship to VIOXX and CELEBREX use were inherently undiscoverable; and, consequently, the discovery rule should be applied to toll the running of the statute of limitations until Plaintiff knew or through the exercise of reasonable care and diligence should have known of the existence of potential claims against Defendants. Plaintiff did not discover, and through the exercise of reasonable care and due diligence, could not have discovered, the true nature of Plaintiff's injuries earlier, nor could Plaintiff have discovered that Plaintiff's injuries were due to the negligent action of the manufacturers of either Vioxx or Celebrex until Merck pulled Vioxx off the market on September 30, 2004.

9. The manufacturers of Vioxx and Celebrex are estopped from relying on any statutes of limitation because of its fraudulent concealment and misrepresentation. Merck

was under a duty to disclose the risks of cardiac and cerebrovascular events associated with the use of Vioxx and Celebrex because this was nonpublic information over which Pharmaceutical Defendants had exclusive control, because the manufacturers knew that this information was not readily available to Plaintiff or plaintiff's doctor and because this information was relevant to Plaintiff and plaintiff's doctor in deciding whether to use Vioxx and Celebrex.

10. Further, Plaintiff did not have knowledge of facts that would lead a reasonable, prudent person to make inquiry to discovery of Defendants' tortuous conduct. Under appropriate application of the "discovery rule", Plaintiffs suit is filed within the applicable statutory limitations period. Moreover, Pharmaceutical Defendants fraudulently concealed from Plaintiffs the nature of the injury and the connection between the injury and Defendants negligent acts in designing, manufacturing, and distributing VIOXX and CELEBREX. This fraudulent concealment tolls the statute of limitations for this action until VIOXX was pulled off the market on September 30, 2004, putting the entire medical community on notice of the problems with clotting discovered to be caused by the entire class of NSAID drugs.

JURISDICTION AND VENUE

11. Defendants are subject to the *in personam* jurisdiction of this Court, and venue is proper herein, by virtue of the fact that Defendants did and continue to do business within the state of Illinois and committed torts in whole or in part in this state against Plaintiff, as more fully set forth herein. Defendants advertised in Illinois and Madison County, made

material omissions and representations in this county, and breached warranties in this county.

12. There is no federal subject-matter-jurisdiction because no federal question is raised and there is no jurisdiction based on diversity of citizenship because Plaintiff and Defendant Walgreens are citizens of the same state.

I. ALLEGATIONS AS TO VIOXX

INTRODUCTION

13. This action arises from the sale and distribution of Vioxx (rofecoxib). Vioxx is the brand name used by Defendant Merck to market and distribute rofecoxib. Vioxx has been proven to cause adverse cardiovascular effects including, but not limited to, heart attack and stroke.

14. Merck during all the times mentioned herein has been engaged in the business of research, licensing, designing, formulating, compounding, testing, manufacturing, producing, processing, inspecting, distributing, marketing, labeling, promoting, packaging and advertising of the prescription drug known as Vioxx for ingestion by consumers. Vioxx was manufactured, sold, designed, supplied, prescribed, distributed, marketed and processed by Defendant, who was at all times acting through their servants, employees, representatives and agents, who placed Vioxx in the market to be purchased and used by the public.

15. Merck participated in, authorized and directed the production and promotion of Vioxx when they knew, or with the exercise of reasonable care, should have known, of the hazards and dangerous propensities of Vioxx and thereby actively participated in the

tortious conduct which resulted in the injuries suffered by the Plaintiff.

16. Vioxx is a member of a class of drugs known as "NSAIDs" (non-steroidal anti-inflammatory drug); but more specifically contains cyclooxygenase 2 ("COX-2") inhibitory properties. Generally, NSAIDs prevent the formation of fatty acid cyclooxygenases, of which there are two known types ("COX-1 and "COX-2"). Vioxx is generally different than NSAIDs in that it is solely a COX-2 inhibitor. The rationale being that if the COX-1 enzyme is unaltered, the patient will experience fewer gastrointestinal complications commonly associated with NSAIDs. Merck marketed, sold, distributed, advertised, and promoted Vioxx for the relief of short term pain contending the drug is safer for the gastrointestinal system than typical anti-inflammatory drugs (NSAIDs) such as ibuprofen.

17. Merck obtained FDA approval for Vioxx on May 20, 1999, for treatment of dysmenorrheal (painful menstrual cramps,) management of acute pain in adults, and relief for the symptoms of osteoarthritis. Merck obtained Vioxx's FDA approval for marketing, sale, and distribution based on inaccurate, false, and misleading information, contained in the New Drug Application, which was on a "fast-track," 6-month approval process to the FDA. Subsequent to this FDA approval, Defendant advertised and marketed Vioxx as safe and effective pain relief medication throughout the United States.

18. Plaintiff, Patty Foreman, received a prescription for Vioxx. Plaintiff took the drug as prescribed by a medical professional for approximately three months, and suffered a heart attack, stroke and cardiovascular injury due to clotting or thrombosis. Plaintiff's use of Vioxx was the direct and proximate cause of the occurrence in question and the injuries

at issue, and/or contributed to cause the injuries at issue.

19. At all relevant times, Plaintiff was ignorant of the dangerous nature of Vioxx, and the adverse cardiovascular effects that could occur due to consumption of and exposure to Vioxx.

20. Merck knew (through its own studies) or should have known that Vioxx contributes to platelet aggregation or clotting, which can lead to catastrophic adverse effects such as myocardial infarctions, ischemic strokes, deep venous thrombosis as well as other medical conditions that result from abnormal clot formation.

21. Through industry and medical studies, unknown to Plaintiff, Merck knew or should have known the adverse cardiovascular effects inherent in Vioxx. Merck ignored or deliberately and fraudulently concealed the increased cardiovascular risk in order to sell Vioxx, avoid the costs of safety precautions, and avoid litigation by people injured by Vioxx. The actions or inactions constitute gross negligence and demonstrate a reckless disregard for the rights and safety of others.

FACTS - VIOXX'S PRE-APPROVAL

22. In the mid to late 1990's Defendant Merck faced the loss of patent protection of its top selling and most profitable drug. In 1996, Merck began plans for a proposed study to prove Vioxx was gentler on the stomach than older painkillers.

23. In need of a new blockbuster drug, Merck pushed forward with plans for the study in spite of statements of the vice president for clinical research Dr. Elise Reicin, who wrote, "The possibility of increased cardiovascular risk (from Vioxx) is of great concern." To remedy this problem and conceal Vioxx's adverse cardiovascular effects,

Merck's V.P. Dr. Reicin proposed people with risk of cardiovascular problems be kept out of the study so the adverse cardiovascular effects would not be evident. Despite all internal knowledge and information relating to cardiovascular-related adverse health effects, Defendant Merck forged ahead aggressively promoting and marketing Vioxx as safe and effective for persons such as Plaintiff in efforts to obtain FDA approval.

24. While it is not clear as to what became of this 1996-97 proposed study, it is clear that Merck concealed its knowledge of the serious cardiovascular risks associated with Vioxx because a successful launch of Vioxx was viewed as financially critical for Merck to retain its current market share, and to sustain stock value. Vioxx's chief competing drug Celebrex (Celecoxib) was placed on the market by Merck competitors Pharmacia and Pfizer three months prior to the launch of Vioxx. Merck's disclosure of the safety concerns over hypertension, thrombosis, edema and/or cardiovascular events would have drastically impacted Merck's positioning in the market.

FACTS - VIOXX'S POST-APPROVAL

25. Merck knew, and had reason to know, of these serious adverse events occurring in patients who took Vioxx at a single dose of 25 mg or at a double dose of 50 mg each. Merck failed to advise the FDA, the medical community, and the patients about these dangerous side effects incident to Vioxx use.

26. Merck intentionally and knowingly chose to market Vioxx, despite its pre-FDA-approval knowledge, its knowledge at product launch, and its post-FDA-approval data thereafter that use of Vioxx carried significant risk factors. These adverse effects were further realized in adverse event reports, in clinical trials where such events were

adjudicated by primary investigators with Merck's assistance, and in numerous studies shortly after market launch which showed statistically significant increases in adverse cardiovascular events among Vioxx users.

27. Merck also omitted the gastrointestinal warning about the possibility of serious gastrointestinal toxicity such as bleeding, ulceration or perforation in patients taking Vioxx.

28. In early 1999, Merck started the 8,000 person VIGOR (Vioxx Gastrointestinal Outcomes Research) study to prove the drug's gastrointestinal safety benefits. The March 2000 VIGOR results revealed precisely what the above discussed internal Merck documents anticipated; a significant increase in the number of blood-clot related problems among Vioxx users. The heart attack rate in the Vioxx group was five times that of the other group taking naproxen.

29. Merck research Chief Dr. Scolnick confessed that there was an inherent risk in Vioxx, and stated in an internal March 9, 2000 subject line "vigor," e-mail that cardiovascular events are "clearly there" and called it a "shame" that it is mechanism (Vioxx) based. Dr. Scolnick recognized that the cardiovascular effects could not have come from naproxen's protective effect. Merck's research chief wrote that like all Merck's big selling drugs, Vioxx too had side effects but assured Merck that they would "do well."

30. However, in March of 2000 Merck issued a news release that the trial's cardiovascular findings were "consistent with" naproxen's favorable effects. To date, and not surprisingly, the only studies to report a protective cardiovascular effect with naproxen are ones funded and assisted by Merck. A number of independent studies have

reported no reduction in risk with naproxen use. In fact, an FDA researcher recently published a report that blatantly contradicts Merck's position and holds naproxen is not protective against coronary heart disease, and if anything, actually confers an increase in risk. Merck intentionally and knowingly made false assertions relating to the VIGOR trial with a blatant disregard for the public welfare all in an effort to conceal Vioxx's adverse cardiovascular effects in order to profit and maintain or gain market position.

31. Merck repeatedly and purposefully downplayed, understated, and concealed the health hazards of Vioxx evident in the VIGOR study. In April of 2000, Merck issued response to the VIGOR results in a news release headlined, "Merck confirms favorable cardiovascular safety profile of Vioxx." This and other similar Merck generated news releases were strategically designed and calculated to deceive and mislead the public about Vioxx's serious adverse effects.

32. In industry sponsored studies presented at the European United League Against Rheumatism (EULAR), an organization in which Merck is a member and corporate sponsor, in June of 2000, it was shown that Vioxx use resulted in a statistically significant increase in hypertension and myocardial infarction. Merck did nothing to publish these studies, which were again reported and denied by Merck as to the hypertension problems in the official publication of the American Pharmaceutical Association, Pharmacy Today, Spin War Aside, Lessons Emerge From COX-2 Trials, in August 2000, page 3.

33. Merck continuously and systematically denied the ill health effects associated with Vioxx while at the same time reaping the profits obtained through the non-disclosure. Merck engaged in an aggressive and expansive advertising and sampling

program and gained continued increases in market share. Merck spent over $160 million on direct-to-consumer television advertising on Vioxx in 2000. The resultant effect for this multi-million dollar advertising blitz combined with Merck's concealing and failing to reveal and warn of the risks was more than $2 billion in profits in the year 2000 alone to Merck and an approximately 23 percent market share.

34. Merck's multi-million dollar advertising campaign created the image, impression, and belief that the use of Vioxx was safe for adults, had fewer side effects and adverse reactions than other pain relief medications and would not interfere with daily life, even though Merck knew these representations to be false. These advertisements, combined with their other promotional literature such as audio conferences, professional meetings, and press releases deceived potential consumers by relaying positive information, including testimonials from satisfied consumers, and manipulated the statistics to suggest widespread acceptability and safety of the product, while intentionally understating the known adverse and serious risks associated with the use of Vioxx. Merck's advertising and marketing campaign conveyed the false impression that Vioxx was a drug of first choice when it should not have been.

35. The FDA's Division of Drug Marketing, Advertising, and Communications ("DDMAC") reviewed the Vioxx promotional activities and materials and "concluded that they are false, lacking in fair balance, or otherwise misleading in violation of the Federal Food, Drug and Cosmetic Act (the Act) and applicable regulations."

36. Most, if not all, of the noted misrepresentations were made in reference to the VIGOR study conducted by Merck. According to DDMAC, Merck "engaged in a promotional campaign for Vioxx that minimizes the potentially serious cardiovascular

findings that were observed in the Vioxx Gastrointestinal Outcome Research (VIGOR) study, and thus, misrepresents the safety profile of Vioxx. Specifically, your promotional campaign discounts the fact that in the VIGOR study patients on Vioxx were observed to have a four to fivefold increase in myocardial infarctions (MIs) compared to patients on the comparator nonsteroidal anti-inflammatory drugs (NSAID), Naprosyn (naproxen)." The Warning Letter was released by the FDA on September 17, 2001, and posted by the FDA on September 21, 2001.

37. The Warning Letter delineated the following misrepresentations made during six promotional audio conferences presented on behalf of Merck by Peter Hold, M.D., which were moderated by Merck employees, a press release, and oral representations made by Merck sales representatives to promote Vioxx. According to the Warning Letter, Merck misrepresented that:

a. The rate of myocardial infarction was minimized. For example, in the June 21, 2000, audio conference, Merck began the discussion of the myocardial infarction rates observed in the VIGOR study by stating: "when you looked at the myocardial infarction global rate, the rate was different for the two groups. The MI rate for Vioxx was 0.4% and if you looked at the Naproxen arm it was 0.1%, so there was a reduction in the MI's in the Naproxen group." Merck then presented an explanation when in fact the situation was not at all that clear. The DDMAC wrote that as Merck knew, "the reason for the difference between Vioxx and Naproxen has not been determined; it is also possible that Vioxx has pro-thrombotic properties."

b. Merck knew that the promotional statement was false because the reason for the difference between the myocardial infarction outcomes for the Vioxx users

versus the Naproxen users had not yet been determined.

c. Merck carefully excluded from the promotional literature that Vioxx may have pro-thrombotic properties, therefore providing an explanation for the increase in adverse cardiac events.

d. Further, DDMAC said that Merck had claimed that the myocardial infarction rate for naproxen was 02% and for Vioxx it was 0.1%, which was completely inaccurate. DDMAC wrote: "Contrary to [Merck's] claim that there was a higher rate of MIs in the naproxen group compared to the Vioxx group, the MI rate for Vioxx in this subpoplation was 12 MIs among 3877 patients (0.3%) as compared to 4 MIs amount 3878 patients (0.1%) for naproxen." The Warning Letter, p. 4.

e. Merck, its agents and/or its representatives falsely claimed that the myocardial infarction rate associated with the use of Vioxx was 0.4% in the VIGOR study, which Merck claimed was basically the same as or a little bit less than the crude myocardial infarction rate of Celebrex in a study involving Celebrex. DDMAC found these Merck claims to be false and misleading.

f. Merck and its agents and representatives misrepresented claims regarding the efficacy of Vioxx as compared to its competitor, Pfizer's Celebrex. When publicly comparing the VIGOR study to a study done on Pfizer's Celebrex known as "CLASS." Merck failed to inform consumers that the patient populations in the two studies, the one performed of Pfizer's Celebrex versus the one performed on Merck's Vioxx, were extremely different. For instance, the VIGOR study excluded patients who had angina or congestive heart failure with symptoms that occurred at rest or with minimal activity as well as patients taking aspirin or other antiplatelet agents. The

Celebrex CLASS study did not exclude these patients, therefore making it more likely that the CLASS trial included patients with a higher risk for myocardial infarction prior to their ingestion of Celebrex. Nevertheless, Merck used the results from the comparison of the two studies VIGOR to CLASS to misrepresent that Vioxx was more effective, safer, and, therefore, a better drug than Celebrex, when indeed, Merck knew that this assertion was false.

g. Merck and its agents and/or its representatives failed to point out that the more affordable alternative, Naproxen, had been statistically proven to produce half as many myocardial infarctions than Vioxx had. These misrepresentations and omissions were made not only at the promotional audio conferences in June of 2000, but also at the annual meeting of the American Society of Health-Systems Pharmacists ("ASHP") in Los Angeles, California, on June 3 through 6, 2001.

38. In the fall of 2000, Merck again sunk to new levels in their efforts to conceal information by employing a barrage of ruthless intimidation and even retaliation tactics against those who spoke out regarding Vioxx's adverse effects. In October of that year, Merck official Louis Sherwood contacted Dr. James Fries, a Stanford University Medical Professor, to inform him that if his "irresponsibly anti-Merck and specifically anti-Vioxx" lectures didn't stop, that he would "flame out." Dr. Fries responded in a letter to Merck chief executive Gilmartin stating, "that Merck had crossed (an ethical) line, that you can't go across." Dr. Fries also explained that several other top medical schools complained of "a consistent pattern of intimidation by Merck" on Vioxx.

39. Dr. Lee Simon, a rheumatologist at Beth Israel Deaconess Medical Center in Boston, reported being the victim of similar type Merck intimidation tactics when he

publicly mentioned data that Vioxx may be associated with a risk of high blood pressure and swelling. Dr. Simon was "shocked that a phone call was made" to his superior to complain that his lectures were slanted against Vioxx; Dr. Simon rightfully believed that Merck was "attempting to suppress discussion about this data."

40. In November of 2000, Merck caused the publication of an incomplete study in the New England Journal of Medicine entitled, "Comparison of Upper Gastrointestinal Toxicity of Rofecoxib and Naproxen in Patients with Rheumatoid Arthritis," and knowingly downplayed and/or withheld from this publication the severity of cardiovascular risks associated with Vioxx consumption over naproxen consumption. The article simply failed to provide critical information about Vioxx related cardiovascular complications such as stroke or blood clots.

41. The year 2001 proved to be more of the same; huge efforts by Merck to conceal and hide Vioxx's adverse effects from the public and, in turn, Merck reaping huge profits. In 2001 Merck spent $135 million to promote the drug in the United States alone; Merck was rewarded with $2.6 billion in revenue making Vioxx the world's tenth biggest selling medicine.

42. In February of 2001, when the FDA revealed results of the VIGOR study, the FDA wanted to highlight the cardiovascular risk prominently on Vioxx's label. Merck resisted and fought hard to maintain its warning/caution free label and the label remained unchanged until April 2002 when Merck and the FDA eventually reached a compromise. Merck's relentless and aggressive efforts to keep the public in the dark enabled them to maintain market position and profits for yet another year, all at the expense of persons such as Plaintiff.

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43. The FDA wrote a "Warning Letter" to Merck on September 17, 2001 (hereinafter, the "Warning Letter"), which demanded that Merck correct the false and misleading messages contained in the promotional campaign for Vioxx, press releases and oral representations made by Merck sales representatives to promote Vioxx.

44. On or about August 29, 2001, JAMA, the Journal of the American Medical Association, published a peer reviewed human epidemiologic study by the Cleveland Clinic Foundation showing that Merck had concealed the risk of a thrombotic cardiovascular event or myocardial infarctions among Vioxx users in Merck's trials at a 95% confidence interval ranged from 2.2 for event-free survival analysis, 2.38 compared to naproxen users, and 4.89 for developing serious cardiovascular events among aspirin patients. See Mukherjee, D., et al., Risk of Cardiovascular Events Associated With Selective Cox-2 Inhibitors, JAMA. 286:8, 954-959, Aug. 22/29, 2001. In addition, the annualized myocardial infarction rates for Vioxx users compared to placebo revealed a statistically significant increase among Vioxx users. Id.

45. In the JAMA study the authors set forth the theory that "by decreasing PG12 production [Vioxx] may tip the natural balance between prothrombotic thromboxane A2 and antithrombotic PG12, potentially leading to an increase in thrombotic events." Id. at 957. In a follow-up peer-reviewed study reported in the Journal of the American College of Cardiology on or about February 6, 2002, Dr. Richard J. Bing conducted scientific testing and confirmed that the COX-2 inhibitor "tips the balance of prostacyclin/thromboxane in favor of thromboxane, leading to increased vascular thrombotic events." Bing, R., & Lomnicka, M., Why Do Cylo-Oxygenase-2 Inhibitors Cause Cardiovascular Events?, J.A.C.C., 39:3, Feb. 6, 2002. This biological plausibility is

further supported by studies completed at the University of Pennsylvania. Cheng, Y., et al., Role of Prostacyclin in the Cardiovascular Response to Thromboxane A2, Journal of Science, V. 296: 539-541, Apr. 19, 2002.

46. The JAMA study's release was followed by a relentless series of publications and peer reviewed literature by Merck employees and consultants again setting forth the blatantly false theory that naproxen had antithrombotic effects which accounted for the appearance of cardiovascular risk among Vioxx users. Again, Merck funded and assisted studies are the only ones to ever make this assertion. This theory has been debunked by numerous respected medical journals and the FDA recently stated that this theory could not be further from the truth.

47. In mid-September, 2001, Merck received a third Warning letter from the FDA stating in part that Defendant's promotional activities are "false, lacking in fair balance, or otherwise misleading in violation of the Federal Food, Drug, and Cosmetic Act (the Act) and applicable regulations." The FDA stated that Merck's promotional campaign "minimizes the potentially serious cardiovascular findings" from a Vioxx study and "misrepresents the safety profile on Vioxx." As to a Merck May 22, 2001, press release, the FDA wrote "your claim in the press release that Vioxx has a 'favorable safety profile' is simply incomprehensible, given the rate of MI [myocardial infarction] and serious cardiovascular events compared to naproxen. The implication that Vioxx's cardiovascular profile is superior to other NSAIDs is misleading; in fact, serious cardiovascular events were twice as frequent in the Vioxx group... as in the naproxen treatment group..."

48. Further, the FDA Warning letter reprimanded Merck for setting forth this false theory relating to the VIGOR study that Naproxen had anti-thrombotic effects, and went

on to state that, "it is also possible that Vioxx has pro-thrombotic effects."

49. Nevertheless, Merck continued its course of action and continued to aggressively market its Vioxx primarily through direct-to-consumer advertising.

50. In the midst of this adverse publicity, Merck took an offensive approach to marketing, providing all Vioxx field personnel with an "obstacle handling guide" to overcome doctors' objections to Vioxx relating to its cardiovascular problems. The training document was appropriately titled "Dodge Ball Vioxx." Merck's massive Vioxx sales force was instructed to avoid and "DODGE" serious, life threatening concerns of both health care professionals and the general public; Merck's corporate philosophy became one of "RUN" and "DODGE" as opposed to being that of "HONEST" and "TRUTHFUL."

51. In April 2002, Merck was required to place information about cardiovascular implications on its Vioxx labeling based on the results of the VIGOR study. In addition, Merck was required to place new label information that Vioxx 50 mg per day is not recommended for chronic use. These warnings were based on information that had been in Merck's possession by approximately January of 2000 at the latest and, as such, Merck did not meet its obligation to provide adequate "direction or warnings" as to the use of Vioxx within the meaning of Section 402 of the Restatement (Second) of Torts or otherwise. Neither did Merck fulfill its alleged obligation to warn the prescribing health care provider of these risks.

52. Internal Merck documents reveal that Merck was set to begin a major cardiovascular study of Vioxx in 2002, but company officials abruptly dropped the project just before it was set to start. This proposed study, which became known as the VALOR

trial was set to begin in June of 2002. However, on March 13, 2002, Merck sent an e-mail to Merck employees worldwide that simply stated the trial was being put on hold and did not cite any details leading to the decision. Although Merck officials have publicly denied it, it is far more than a coincidence that their decision to cancel the trial fell amidst their negotiations with the FDA over the April 2002 cardiovascular warnings mentioned above. Merck's decision to cancel the VALOR trial is in concert with their corporate strategy to conceal information relating to Vioxx's adverse cardiovascular effects.

53. In the summer of 2002, Merck conducted its most inflammatory and aggressive measures via their intimidation and retaliation tactics to suppress and conceal speech and publicity relating to the adverse cardiovascular effects of Vioxx. Dr. Laporte of the Catalan Institute of Pharmacology in Barcelona, Spain, had published his criticisms of Merck's handling of Vioxx. Merck then had the audacity to send him a "rectification" that they insisted Dr. Laporte publish, which Dr. Laporte refused. Merck then filed suit against the doctor in Spanish Court demanding a public correction. In early 2004 the judge ruled that the publication accurately reflected the cardiovascular safety (or lack thereof) of Vioxx and ordered Merck to pay all court costs.

54. In October of 2002, the prestigious British medical journal *Lancet* published a study that analyzed the medical data of close to 300,000 people and determined that people who take Vioxx are almost twice at risk of developing heart disease, including heart attack. *Lancet* also concluded that there was no anti-thrombotic or protective effect of naproxen, effectively discounting Merck's theory. Merck again opted not to publicize or warn of these findings, and would stick to its same story for another two years. Merck would continue to spend more than $100 million annually in direct-to-consumer

advertising, and expand its distribution to more than 80 countries.

55. On August 25, 2004, FDA researcher Dr. David Graham presented at a medical conference the results of a database analysis of 1.4 million patients that concludes Vioxx users are more likely to suffer a heart attack or sudden cardiac death than patients taking Celebrex. In fact, the report shows there is a 3.7-fold increase in risk compared with those taking Celebrex. With 92,791,000 prescriptions for Vioxx filled between 1999 and 2003, the FDA conservatively estimates an excess of 27,785 cases of AMI (Acute Myocardial Infarction) and SCD (Sudden Cardiac Death) for those years alone. Plaintiff is one of those 27,785 cases.

56. Merck was still not ready to concede the truth. On August 26, 2004, true to form, Merck attempted to minimize and downplay the adverse findings and authorized a press release refuting Dr. Graham's study entitled, "Merck stands behind the efficacy and overall safety and cardiovascular safety of Vioxx."

57. On September 23, 2004, Merck claims it had an epiphany. Merck had been sponsoring a small 2600 patient (APPROVe) study to in order to gain additional FDA approval for Vioxx to treat the recurrence colon polyps. The APPROVe study was stopped prematurely on the instruction of the data and safety monitoring board after the investigators found that after 18 months of treatment, patients taking Vioxx had twice the risk of a myocardial infarction compared with those receiving placebo. Merck alleges that this small study which was by no means intended to test for Vioxx's overall safety is what triggered the collapse of all their previous defenses. The results of the APPROVe study combined with mounting pressure from the FDA compelled Merck to finally acknowledge Vioxx's dangerous propensities. Merck then opted to back out rather than be

forced out.

58. On September 30, 2004, Merck withdrew Vioxx from the U.S. and the more than 80 countries around the in world. This came only after an estimated 80 million patients had taken the drug and Merck's annual sales had topped $2.5 billion. This represents the largest prescription drug withdrawal in history.

SUMMARY

59. Critics have described the rise and fall of Vioxx as a cautionary tale of masterful public relations and aggressive marketing. At all times relevant to this litigation, Defendant Merck had a significant market share based upon claims of Vioxx's efficacy, a very aggressive marketing program which included financial incentives to sales teams, infusion of some 700 new sales representatives, and a massive direct-to-consumer advertising and physician sampling program.

60. As a result of such marketing, Vioxx gained a significant market share in competition with Celebrex that Merck would not have gained if Merck had not suppressed and concealed information about Vioxx and/or made false representations of Vioxx's superiority and efficacy.

61. If Defendant had not engaged in this conduct, prescribers like Plaintiff's Physician would not have prescribed Vioxx and patients, like Plaintiff, would have switched from Vioxx to safer products or would have refrained wholly from any use of Vioxx.

62. From approximately 1999 through September 30, 2004, Defendant continued to engage in a common scheme in marketing, distributing and/or selling Vioxx under the guise that it was safe and efficacious for persons such as Plaintiff before, during and after Plaintiff experienced this confirmed adverse cardiovascular event.

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63. Plaintiff alleges that the marketing strategies, including without limitation the detail and sampling programs and direct-to-consumer advertising, of the Defendant targeted Plaintiff to purchase Vioxx. At the time the Defendant distributed, manufactured and marketed Vioxx, Defendant intended that Plaintiff and Plaintiff's health care professional would rely on the marketing, advertisements and product information propounded by Defendant.

64. The actions of Defendant, in failing to warn of the clear and present danger posed to others by the use of its drug Vioxx, in suppressing evidence relating to this danger, and in making deliberate and misleading misrepresentations of fact to minimize the danger or to mislead prescribing physicians and patients as to the true risk, are the direct and proximate cause of Plaintiffs injuries. Plaintiff seeks compensation for the damages they have sustained relating to Plaintiff's past, present, and future physical pain and mental anguish, loss of earning capacity, disfigurement, physical impairment, and medical care expenses. Additionally, the actions of Defendant constitute gross negligence and a reckless disregard for the lives of others.

COUNT 1-COMMON LAW STRICT LIABILITY-

AGAINST MERCK

COMES NOW Plaintiff and for Count One of the Complaint against Defendant Merck alleges:

65. The Plaintiff re-alleges and incorporates the foregoing allegations.

66. In addition to pleading negligence, Plaintiff pleads the doctrine of strict liability. Defendant is strictly liable to Plaintiff under Section 402A, Restatement (Second) of Torts, for the defective design of the Vioxx. At the time Vioxx was designed,

manufactured and sold by said Defendant, safer alternative designs existed, which included designs other than those actually used, that had they been selected by said Defendant, would have prevented or significantly reduced the likelihood of Plaintiff's injuries, and such designs were both economically and technologically feasible at the time these products left the possession of said Defendant, and had they been used, would have not have impaired the utility of the product. Defendant's defectively designed drug was a producing cause of the occurrence in question and Plaintiff's injuries.

67. Defendant is strictly liable to Plaintiff under Section 402A, Restatement (Second) of Torts, for the defective marketing of Vioxx. Defendant failed to provide adequate warnings and instructions for safe use of Vioxx. Defendant's defectively marketed drug was a producing cause of the occurrence in question and Plaintiff's injuries.

68. Defendant Merck is also strictly liable to Plaintiff under Section 402B of the Restatement (Second) of Torts in misrepresenting to the public that its product was safe and without defect, which statement and representation was false and involved a material fact concerning the character of quality of the product in question, and upon which representations the consumer constructively relied, and which constituted a producing cause of the injury at issue.

69. Further, each of the above and foregoing acts or omissions of Defendant were more than momentary thoughtlessness, inadvertence, or error of judgment. Such acts or omissions constituted such entire want of care as to establish that the acts or omissions were the result of actual conscious indifference to the rights, safety, or welfare of the person or persons affected. Plaintiff is entitled to recover judgment against Defendant.

WHEREFORE, Plaintiff prays for judgment against Defendant in a sum in excess

of Fifty Thousand Dollars ($50,000.00), for such other relief as may be fair and reasonable under the circumstances and for Plaintiff's costs herein expended.

COUNT 2- NEGLIGENCE AND GROSS NEGLIGENCE-

AGAINST MERCK

COMES NOW Plaintiff and for Count Two of the Complaint against Defendant Merck, alleges:

70. The Plaintiff re-alleges and incorporates the foregoing allegations.

71. The Plaintiff would further show that at all times material hereto, the manufacture, sale, design, supply, distribution, or prescription of Vioxx with which Plaintiff came in contact, was under the exclusive control of the Defendant, their agents, servants and employees, and that had the Defendant herein not been guilty of negligence, the Plaintiff would not have sustained Plaintiff's injuries. Accordingly, the Plaintiff is entitled to recover from the Defendant under the doctrine of res ipsa loquitur.

72. The law imposed a duty on the Defendant, as a manufacturer and marketer of pharmaceutical drugs, to exercise reasonable care. The Defendant knew, or in the exercise of ordinary or reasonable care ought to have known, that Vioxx it manufactured, sold, designed, supplied, distributed, promoted, or marketed was dangerous, unsafe, and highly harmful to Plaintiff's health, notwithstanding which:

a. Defendant negligently failed to design a reasonably safe product;

b. Defendant negligently placed Vioxx into the market;

c. Defendant negligently failed to remove Vioxx from the market;

d. Defendant negligently failed to fund and conduct medical and scientific studies to determine the risks of the overall safety of Vioxx, in the alternative, failed to

heed the warnings and risks of Vioxx;

e. Defendant negligently failed to conduct sufficient testing on Vioxx that would have shown Vioxx had serious side effects, including, but not limited to the cardiovascular events described above;

f. Defendant negligently failed to conduct adequate post-marketing surveillance to determine the overall safety of Vioxx;

g. Defendant negligently failed to accurately disclose the results of their post-marketing surveillance to advise the Plaintiff, consumers, and the medical community of the aforementioned risks to individuals when the drugs were ingested;

h. Defendant negligently failed to investigate the adverse event reports relating to Vioxx;

i. Defendant negligently marketed their products;

j. Defendant negligently failed to provide Plaintiff with visible, understandable warnings that were adequate to convey and alert Plaintiff the severity of the risks and serious thrombotic cardiovascular side effects of Vioxx ingestion;

k. Defendant negligently failed to take any reasonable precautions or exercise reasonable care to warn Plaintiff of the potential risks and serious thrombotic and cardiovascular side effects of Vioxx ingestion;

l. Defendant negligently failed to take any reasonable precautions or exercise reasonable care to warn Plaintiffs health care providers of the potential risks and serious thrombotic and cardiovascular side effects of Vioxx ingestion;

m. Defendant negligently failed to take any reasonable precautions or exercise reasonable care to warn the health care industry of the potential risks and

serious thrombotic and cardiovascular side effects of Vioxx ingestion;

n. Defendant negligently failed to provide adequate post-marketing warnings or instructions after the Defendant knew or should have known of the significant risks of personal injury and death as identified herein among other serious side effects from the use of Vioxx;

o. Defendant negligently failed to warn Plaintiff that Vioxx should not be used in conjunction with any risk factors for these adverse events such as a family history of ischemic heart disease, or risk factors for ischemic cardiovascular disease; and,

p. Defendant negligently failed to warn Plaintiff that they undertook the risk of adverse events and death relating to Vioxx as described herein

73. The Defendant's acts of negligence, as described above but not limited to these specific acts, proximately caused the Plaintiff's injuries and the occurrence in question.

WHEREFORE, Plaintiff prays for judgment against Defendant in a sum in excess of Fifty Thousand Dollars ($50,000.00), for such other relief as may be fair and reasonable under the circumstances and for Plaintiff's costs herein expended.

COUNT 3- NEGLIGENCE- SALE OF PRODUCT-

AGAINST MERCK

COMES NOW Plaintiff and for Count Three of the Complaint against Defendant Merck, alleges:

74. The Plaintiff re- alleges and incorporates the foregoing allegations.

75. Defendant, during some or all relevant times, manufactured, sold, marketed, and/ or distributed Vioxx that was supplied to the Plaintiff for use.

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76. The Plaintiff had the duty, as product sellers, to exercise reasonable care for the safety of the Plaintiff.

77. These duties included the responsibility for the following safety and health matters relating to Vioxx:

a. the investigation of the health risks;

b. writing and publishing adequate and timely precautionary product labels and other health and safety information;

c. writing and publishing adequate and timely specifications and standards about the true risks of injury associated with the products;

d. writing and publishing adequate and timely specifications and standards about the symptoms of such injuries

e. writing and publishing adequate and timely specifications and standards about the scope of such injuries

f. writing and publishing adequate and timely specifications and standards about the severity of the known risks associated with the products.

78. The Defendant knew, or in the exercise of reasonable care should have known, that Vioxx would cause adverse cardiovascular effects to its consumers like the Plaintiff.

79. The Defendant breached its duty of reasonable care to the Plaintiff and was negligent, without regard to whether the acts were intentional, knowing, malicious, or reckless.

80. Defendant's negligent acts and omissions were the direct and proximate causes of the occurrence in question and Plaintiff's injuries and damages.

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WHEREFORE, Plaintiff prays for judgment against Defendant in a sum in excess of Fifty Thousand Dollars ($50,000.00), for such other relief as may be fair and reasonable under the circumstances and for Plaintiff's costs herein expended.

COUNT 4 - BREACH OF WARRANTIES (EXPRESS and IMPLIED)

AGAINST MERCK

COMES NOW Plaintiff and for Count Four of the Complaint against Defendant Merck, alleges:

81. The Plaintiff re- alleges and incorporates the foregoing allegations.

82. Merck through descriptions, affirmations of fact, and promises relating to their Vioxx drugs to the FDA, prescribing physicians, and the general public, including the Plaintiff, expressly warranted that Vioxx was both safe and efficacious for its intended use.

83. These warranties came in the form of:

a. Publicly made written and verbal assurances of the safety and efficacy of Vioxx by Merck;

b. Press releases, interviews and dissemination via the media of promotional information, for the sole purpose of which was to create an increased demand for Vioxx, which failed to warn of the risks inherent to the ingestion of Vioxx;

c. Verbal assurances made by Merck regarding Vioxx and the downplaying of any risk associated with the drug;

d. False and misleading written information, supplied by Merck, and published in the Physician's Desk Reference on an annual basis, upon which physicians

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